REMARKS

Claims 1, 3-18 and 21-33 are pending. By this Amendment, claims 1 and 21 are amended, claims 19 and 20 are canceled (claim 2 having been canceled previously), and claims 22-33 are added. No new matter has been incorporated into the application as a result of the amendments made herein.

A restriction requirement was made in the first Office Action. Applicants hereby confirm the previous restriction requirement and election. Claims 3, 4, 7, 9, 11, 13, 15, and 17 were previously withdrawn as being drawn to non-elected subject matter and remain withdrawn. New claims 31-33 are also drawn to non-elected subject matter, and therefore Applicants agree to withdraw them from present consideration until allowance of generic subject matter.

In the Office Action, claims 1, 5, 6, 10, 14, and 16 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,050,266 to Benetti et al. (Benetti). The Office Action states that Benetti teaches a tissue approximation device having two elongate arms 3, an attachment means 16, adhesive pads 4 and a locking means 18 as claimed. Applicants request reconsideration and withdrawal of this rejection in view of the following remarks.

Benetti's device is used to stabilize the motion of the heart using mechanical instruments specifically designed to apply a stabilizing force to the heart to minimize motion of the beating heart during a surgical procedure, as explained in col. 3, lines 2-5. The device includes two contact members 1 that are attached to a connecting shaft 2 connected to shaft means 3. The shaft means 3 are interconnected at a pivot point 16. The length of the shaft means 3 is adjustable by telescoping shafts 18, 19 that may have a conventional locking mechanism. As stated in col. 8, lines 36-44, the contact members 1 preferably have friction means 4 associated with their bottom surface 5 such that the contact members 1 more securely engage the beating heart when a stabilizing force is exerted on the shaft means 3. **The friction means 4 preferably comprises a textured surface covering the bottom surface 5 of the contact member 1, and may be**

comprised of several bio-compatible substances such as a textured rubber, textured or ridged aluminum, stainless steel or the like. There is no disclosure that the textured surface 4 is adhesive. Further, adhesive is not a similar material to textured rubber, textured or ridge aluminum or stainless steel. Thus, the rejection is in error. Each and every feature of claims 1, 5, 6, 10, 14, and 16 is not disclosed in Benetti; thus, the rejection should be withdrawn.

It is further noted that there would be no motivation to change Benetti's textured surface to adhesive since the device is intended to apply a force to the heart and not to adhere to skin or hold a wound closed. There is no suggestion in the prior art to contact the heart with an adhesive device to stabilize a beating heart.

Claims 12 and 18 were rejected under 35 U.S.C. §103(a) as being unpatentable over Benetti in view of U.S. Patent No. 4,821,719 to Fogarty. The Office Action adds Fogarty to teach of a device having an adhesive pad with a first surface 30a and a second surface 55 with male and female connecting mechanisms and asserts that it would have been obvious to provide releasable adhesive pads in Benetti in view of Fogarty.

Fogarty's device is directed to a vessel occluding instrument that has resilient pads 30 secured to the clamp ends of a pair of jaws. The embodiment identified in the Office Action, seen in Figs. 5 and 6, has a pad 30a with Velcro like loops on an elastomeric tube 54 having a passage 55 to slide over the distal end 52 of the clamp. First, there is no adhesive pad. Second, Fogarty's device clamps around a vessel and does not have an open position and a closed position in which adhesive pads, or any pads for that matter, are parallel and non-contiguous to each other. So, Fogarty does not remedy the deficiencies of Benetti. Further, there would be no motivation to modify Benetti in view of Fogarty as Benetti's device would not function with Velcro-like clamping jaws. For at least these reasons, Benetti as modified by Fogarty, if shown to be possible, does not render claims 12 and 18 obvious.

Claims 8 is rejected under 35 U.S.C. §103(a) as being unpatentable over Benetti in view of U.S. Patent No. 3,754,331 to Agnone. The Office Action cites Agnone as teaching of connecting pads to forceps with a ball and socket connection.

Agnone's forceps are designed for dental extraction. Beaks 22 and 24 are mounted on handle elements 12 and 14, respectively, and can be adjusted to engage a tooth by manipulating screws 30 and 32 that end in a ball and socket joint 36. There are no adhesive pads and no elements that are mounted parallel and non-contiguous to each other. There is no reasonable basis for suggesting that one of ordinary skill in the art of Benetti's device would look to a dental extraction device that has a hand manipulated beak for any modification. A curved clamping beak of a dental instrument would not be used to apply a stabilizing force to a beating heart. Further, there would be no way to manipulate the beak within a surgical chest cavity. Moreover, there is no suggestion in the prior art to add a ball and socket joint to Benetti. Finally, even if such a combination could be made, the features of the claims would not be met as Agnone does not remedy the deficiencies of Benetti, since no adhesive pads are taught. Claim 8 is not rendered obvious by the asserted combination.

Claims 1 and 19-21 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 6,042,599 to Huttner et al. (Huttner) in view of U.S. Patent 3,926,193 to Hasson.

Huttner's forceps are formed of a single handle 16 with a pair of legs 27 and 28 that extend perpendicular to the handle and have offset portions 30, 31. Rigidly mounted to the lower ends of the offset portions are grip members 36 and 39. Each grip member 36, 39 has a grip surface 37, 40 including a plurality of parallel, longitudinally extending, generally V-shaped projections 42. Hasson's closure device uses a pair of tape members connected by tie member anchors and slides. The Office Action asserts that Huttner discloses a device as claimed with pads 43, 44 and that it would have been obvious to make the pads of adhesive material in view of Hasson's device that uses adhesive 12. However, the combination of references does not disclose or suggest the device of claim 1 or the process of claim 21.

In particular, claim 1 is directed to a tissue approximation device comprising two elongate arms, an attachment means to secure the elongate arms to each other at one or more locations, adhesive pads movably connected on the ends of the elongate arms to anchor the tissue approximation device to the skin, and a locking means to lock the elongate arms in place relative to each other. The adhesive pads are spaced apart from the one or more locations of the attachment means in the direction of the elongate arms. The tissue approximation device has an open and a closed position, and when in the closed position, the adhesive pads are parallel and non-contiguous to each other.

In Huttner, the surfaces that contact the skin surface are rigidly mounted in a fixed position to the supports. This poses several problems. First, if the surface of the skin is not precisely level, the contact surfaces will fail to make complete or secure contact with the skin surrounding the wound. As even a layman will recognize, there are very few portions of the human body, if any at all, that present a perfectly level skin surface. Second, Huttner's forceps must be held in only one position to hope to make full contact with the skin surface. This requires limited access to the patient by the medical personnel and may be difficult to accurately achieve depending on the location of the wound and environmental factors affecting the patient, such as ongoing contemporaneous medical procedures. Huttner does not disclose adhesive pads movably connected on the ends of elongated arms, as recited in claim 1. Further, Huttner modified with adhesive pads such as Hasson's, as suggested in the Office Action, also does not disclose or suggest of adhesive pads movably connected on the ends of elongated arms. There is no suggestion in the prior art to redesign Huttner's forceps to use adhesive pads movably connected on the ends of elongated arms. Absent such a suggestion, a prima facie case of obviousness cannot be made. Claim 1 is allowable.

Claim 21 is directed to a method for closing a wound in the surface of a patient's skin, comprising the following steps. A tissue approximation device is provided that comprises two elongate arms, an attachment means to secure the elongate arms to each other at one or more locations, and a locking means to lock the elongate arms in place relative to each other. Providing the tissue approximation device includes connecting an adhesive pad to an end of each elongate arm and adjusting a position of each pad relative

to the skin surface. The adhesive pads are spaced apart from the one or more locations of the attachment means in the direction of the elongate arms. The tissue approximation device has an open and a closed position, and when in the closed position, the adhesive pads are parallel and non-contiguous to each other. The process also includes positioning the adhesive pads to skin on opposed sides of a wound, approximating the wound by actuating the tissue approximation device in a direction to move the adhesive pads towards each other in a common plane that is generally parallel to the skin tissue, engaging the locking means to assure that the edges of the wound do not move, applying a topical skin closure adhesive to the wound, and removing the adhesive pads from the skin surface.

Huttner, even if modified with adhesive pads as suggested in the Office Action, does not disclose or suggest of the method recited in claim 21. There is no step of connecting an adhesive pad to an end of an elongate are and adjusting the position of the pad relative to the skin surface. Huttner's grip surfaces are rigidly mounted with respect to the handle. Even Huttner's second embodiment in which the grip surfaces 60, 62 are angled with respect to the skin surface are shown rigidly fixed in position with respect to the handle. Clearly Huttner has not contemplated that the grip surfaces can be movable. Without a suggestion in the prior art, a prima facie case of obviousness cannot be made. The method of claim 21 is allowable.

New claims 22-33 are patentable over the prior art also. Claim 22 is directed to a tissue approximation device for application to a skin surface adjacent to a wound comprising a pair of arms, with each arm having a longitudinal axis and opposed ends, wherein one end includes a handle and the other end includes a tong with a connector. An attachment mechanism is coupled to each arm that movably couples the arms to each other so that a distance between each tong is selectively variable. An adhesive pad is removably coupled to the connector of each tong, wherein each adhesive pad has an adhesive surface that extends in a plane generally parallel to the longitudinal axis of the respective tong, the adhesive surface having a high shear resistance for holding the skin surface and a low peel resistance for removal from the skin surface. The connectors support the adhesive pads to be positionable in a common plane on opposed sides of the wound and conform to the skin surface adjacent to the wound. A locking mechanism

coupled to each arm to selectively lock the pair of arms in a fixed position relative to each other. None of the prior art references disclose or suggest of such a device, especially a device having a tong with a connector to removably couple an adhesive pad or that supports an adhesive pad to be positionable in a common plane on opposed sides of a wound and conform to the skin surface adjacent to the wound. All of the prior art devices for contacting a skin surface are rigid clamps and do not disclose this use of adhesive or the use of a movable contact surface.

It is submitted that the application is in condition for allowance. Should further issues requires resolution prior to allowance, the Examiner is requested to telephone the undersigned.

Respectfully submitted,

Caroline D. Dennison
Reg. No. 34, 494
Attorney for Applicants
703-584-3267 (direct line)

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CORRESPONDENCE ADDRESS:
Philip S. Johnson, Esq.
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, N.J. 08933-7003